K012884

JAN 17 2002

510(k) SUMMARY

510(k) NUMBER:	PENDING
SUBMITTED BY:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000
CONTACT PERSON:	Anil Bhalani Vice President of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	August 27, 2001
NAME OF DEVICE:	Dilating Tip Obturator
CLASSIFICATION NAME:	Laparoscope, General & Plastic Surgery (21CFR 876.1500)
TRADE NAME:	Dilating Tip Obturator
PREDICATE DEVICE:	EndoPath Optiview Optical Surgical Obturator, Ethicon-Endo-Surgery, Inc. Cincinnati, OH.

INTENDED USE: The Dilating Tip Obturator is a sterile single use device, intended for use in conjunction with Applied's currently marketed Trocar products to establish a path of entry for endoscopic instruments for use during general, abdominal, gynecological and thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments.

DEVICE DESCRIPTION: The Dilating Tip Obturator is a sterile single use device, intended for use in conjunction with Applied's currently marketed Trocar products. A standard trocar assembly consists of an obturator, a seal and a cannula system. Traditional obturators use a blade for cutting to establish a path of entry through the several layers of tissue. The Dilating Tip Trocar dilates and separates tissue along its natural fiber lines in its path of entry.

The Dilating Tip Obturator will be available in sizes of 5mm, 11mm and 12mm diameter in lengths ranging from 55mm to 150mm.

The use of the Dilating Tip Obturator, which separates tissue along its natural fibers versus cutting of tissue by traditional bladed trocars is expected to reduce trauma to vessels and the abdominal wall and minimize the risk of organ puncture. Upon removal of the trocar at the end of the procedure the separated tissue is expected to reapproximate, leaving a smaller, linear defect.

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PERFORMANCE DATA SUMMARY: The performance and functional testing of the Dilating Tip Obturator included tests to verify the insertion force and tests to verify its reliability during use. The performance and functional testing demonstrated that the Dilating Tip Obturator is substantially equivalent to its predicate devices and it introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Anil Bhalani
Vice-President of Regulatory Affairs and Clinical Programs
Applied Medical
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K012884
Trade Name: Dilating Tip Obturator
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 26, 2001
Received: November 28, 2001

Dear Mr. Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012884

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Dilating Tip Obturator "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Dilating Tip Obturator

Indications for Use: The Dilating Tip Obturator is indicated for use in general, abdominal, gynecological and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.

Signature: _____ Title: *Vice President of RA/Clinical Programs* Date: *8-27-01*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for _____
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012884